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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,810	11/17/2003	Shengwen Li	ALLE0004-100 (17614(BOT))	5198
34132	7590	03/07/2006	EXAMINER	
COZEN O'CONNOR, P.C. 1900 MARKET STREET PHILADELPHIA, PA 19103-3508			KAM, CHIH MIN	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,810	LI ET AL.	
	Examiner	Art Unit	
	Chih-Min Kam	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,5-7,9-11,18-21 and 75-80 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,5-7,9-11,18-21 and 75-80 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11/17/03 & 5/12/04 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------|-----------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Request for Continued Examination (RCE) filed on January 20, 2006 under 37 CFR 1.114 is acknowledged. An action on the RCE follows.

Status of the Claims

2. Claims 1, 5-7, 9-11, 18-21 and 75-80 are pending.

Applicants' amendment filed January 20, 2006 is acknowledged. Applicants' response has been fully considered. Claims 1, 5, 7 and 18-21 have been amended, claims 73 and 74 have been cancelled, and new claims 75-80 have been added. Therefore, claims 1, 5-7, 9-11, 18-21 and 75-80 are examined.

Maintained-Informalities

The disclosure is objected to because of the following informalities:

3. Fig. 2 is objected to because the drawing recites the peptide sequence of SEQ ID NO:5 being SEQ ID NO:39, which is not correct. Appropriate correction is required.
4. The specification recites amino acid and nucleotide sequences at pages 25 (e.g., tetrapeptides), 26, 37 and 38, however, there are no sequence identifiers "SEQ ID NO:" provided. Applicants must comply with the requirements of the sequence rules (37 CFR 1.821-1.825) and provide a new copy of sequence listing and CRF containing all the sequences.

Response to Arguments

Applicants indicate they will submit a revised sequence listing and a revised Fig. 2 under a separate cover (page 5 of the response). However, the drawing and sequence listing have not been received, the objection is maintained until the correction is made.

Withdrawn Claim Rejections - 35 USC § 112

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5. The previous rejection of claims 18-21, under 35 U.S.C. 112, second paragraph, regarding insufficient antecedent basis, is withdrawn in view of applicants' amendment of the claim in the amendment filed January 20, 2006.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1, 5-7, 9-11, 18-21 and 75-80 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claims 1, 5-7, 9-11, 18-21 and 75-80 are indefinite as to the claim recites the term "wherein the effective amount of the glycosylated inactive botulinum toxin is an amount of glycosylated inactive botulinum toxin sufficient to compete with an active botulinum toxin for binding to a cell surface receptor, translocation through an endosomal membrane, cleavage of a SNAP-25 protein, cleavage of a synaptobrevin (VAMP) or cleavage of a syntaxin, thereby reducing the ability of the active botulinum toxin to intoxicate a neuron." It is not clear if the glycosylated inactive botulinum toxin has an amount effective to compete with an active botulinum toxin for cleavage of a SNAP-25 protein, cleavage of a synaptobrevin (VAMP) or cleavage of a syntaxin, then how the inactive botulinum toxin would intoxicate a neuron. Claims 5-7, 9-11, 18-21 and 75-80 are included in this rejection for being dependent on a rejected claim and not correcting the deficiency of the claim from which they depend.

Response to Arguments

Applicants indicate the claims have been amended to recite the effect of using an effective amount of a glycosylated inactive botulinum toxin, which is supported by the specification (see paragraphs [0010] to [0013], [0043]), and the outcome of the treatment (pages 5-6 of the response).

Applicants' response has been considered, however, the argument is not fully persuasive because although the missing steps have been added, the statement that the inactive botulinum toxin can compete with an active botulinum toxin for cleavage of a SNAP-25 protein, cleavage of a synaptobrevin (VAMP) or cleavage of a syntaxin appears to be contradict to the term "inactive botulinum toxin".

Conclusion

8. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Chih-Min Kam, Ph. D.
Patent Examiner



CHIH-MIN KAM
PATENT EXAMINER

CMK

March 3, 2006